

Applicants: Rolando Pajon Feyt, et al.  
Serial No.: 10/580,888  
Filing Date: May 25, 2006  
Docket No.: 976-33 PCT/US/RCE  
Response to final office action issued July 25, 2008  
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### **REMARKS**

Prior to the present amendment, claims 1- 31 and 46 were canceled; claims 32, 35, and 45 were amended; and claims 32-45 were pending. By the present amendment, applicant has amended claims 32 and 35, and canceled claims 33, 34, 39, 41, and 42. No new matter has been added. Accordingly, claims 32, 35-38, 40, 43-45, 47, and 48 are under examination.

#### **Rejection of claims 32, 35-45 under 35 U.S.C. § 112, first paragraph**

On page 5 of the office action, the examiner rejects claims 32-45 under 35 U.S.C. § 112, first paragraph. The examiner states that the application is enabled for a method for inducing an immune response against an infection caused by *Neisseria meningitidis* or *N. gonorrhoeae* in a human in need thereof by administering SEQ ID NO: 4. However, the examiner asserts that the specification does not reasonably enable inducing an immune response against other *Neisseria* species.

Merely in order to expedite prosecution, applicants have canceled claims 33 and 34, and amended claims 32 and 35 to include a method for inducing an immune response against an infection caused by *N. meningitidis* or *N. gonorrhoeae*. Applicant submits that the specification reasonably enables one skilled in the art to make and use the claimed invention. Applicants respectfully request that the examiner reconsiders and withdraws the rejection.

#### **Rejection of claims 32-36, 39-40, and 42-45 under 35 U.S.C. § 102(b)**

On page 3 of the office action, the examiner rejects claims 32-36, 39-40, and 42-45 under 35 U.S.C. § 102(b) in view of Fraser, et al. (WO 99/57280). The examiner states that

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Fraser teaches a method of treating and preventing a *Neisseria* infection that includes administering a protein comprising an amino acid sequence set forth in SEQ ID NO: 4 of the present application (SEQ ID NO: 1522 of Fraser).

Applicants respectfully disagree. "In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a reference contains an 'enabling disclosure'... ." (citations omitted). "The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation." *MPEP* § 2121.01

The Fraser reference fails to be an anticipatory reference because it is not an enabling disclosure. The Fraser reference merely discloses and claims over 3000 sequences that were identified through computer analysis (see, for example, pages 52-53 of Fraser). One skilled in the art would not be able to extrapolate which of the over 3000 disclosed sequences identified through computer analysis would have yielded a predictable immunological properties *in vivo*. The reference fails to provide a specific description as well as enablement of the subject matter of the claims at issue. More specifically, the Fraser reference fails to teach which sequence or fragment is of predictable relevance for a method of inducing an immune response against a *N. meningitidis* or *N. gonorrhoeae* infection in a human in need thereof.

The discovery of which method and what sequence or fragment is required to arrive at the claimed invention would have been sufficiently arduous for one skilled in the art in view

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of the Fraser reference and its over 3000 disclosed sequences. The reference fails to clearly and unequivocally disclose the claimed invention and fails to direct those skilled in the art to the invention without any need for picking or choosing from the vast number of sequences. Fraser does not provide sufficient guidance. Absent such guidance, undue experimentation would be required. As the *MPEP* § 2121.01 states, “mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation.”

Accordingly, the Fraser reference is not an anticipatory reference and does not anticipate the claims. Applicants respectfully request reconsideration and withdrawal of the rejection.

**Rejection of claims 32-36, 39-40, and 42-45 under 35 U.S.C. § 103(a) in view of the Fraser and Tai references**

On page 7 of the office action, the examiner rejects claims 32-40 and 42-45 under 35 U.S.C. § 103(a) as being unpatentable over Fraser, et al (WO 99/57280) in view of Tai, et al (WO 97/28273).

Applicants respectfully disagree. The lack of an enabling disclosure in Fraser (as discussed above) and the unpredictable *in vivo* properties of proteins weigh in favor of nonobviousness. The cited references, individually and in combination, fail to provide reasonable prediction of which sequence out of the 3000 computer generated sequences would exhibit the *in vivo* properties to arrive at the claimed invention. The Tai reference fails to compensate for the deficiencies of the Fraser reference.

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Only with hindsight knowledge can it be argued that it would have been obvious to select and use a recombinant protein comprising an amino acid sequence set forth in SEQ ID NO: 4 having properties for use in a method of inducing an immune response against an infection caused by *N. meningitidis* or *N. gonorrhoeae* in a human in need thereof. The application of hindsight is inappropriate where the prior art does not suggest that this protein could be reasonably expected to manifest the properties and advantages for use in the claimed invention.

Accordingly, the claims are not unpatentable under 35 U.S.C. § 103(a). Applicants respectfully request reconsideration and withdrawal of the rejection.

**Rejection of claims 32-36, 39-40, and 42-45 under 35 U.S.C. § 103(a) in view of the Fraser and Meinke references**

On page 9 of the office action, the examiner rejects claims 32-36 and 39-45 under 35 U.S.C. § 103(a) as being unpatentable over Fraser, et al (WO 99/57280) in view of Meinke, et al (WO 01/059148). The examiner acknowledges that the Fraser reference does not teach a pharmaceutical composition that further comprises a hormone. The examiner relies on the Meinke reference to compensate for such deficiencies.

Applicants respectfully disagree. The lack of an enabling disclosure in Fraser (as discussed above) and the unpredictable *in vivo* properties of proteins weigh in favor of nonobviousness. The cited references, individually and in combination, fail to provide reasonable prediction of which sequence out of the 3000 computer generated sequences

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would exhibit the *in vivo* properties to arrive at the claimed invention. The Meinke reference fails to compensate for the deficiencies of the Fraser reference.

Merely in order to expedite prosecution, applicants have canceled claims 41 and 42, which were directed to the claimed method wherein the pharmaceutical composition further comprise a hormone and growth factor, respectively. Accordingly, the rejection and reliance on the Meinke reference is moot.

The remaining claims are not unpatentable under 35 U.S.C. § 103(a) in view of the cited references. Applicants respectfully request reconsideration and withdrawal of the rejection.

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**Conclusion**

In view of the foregoing amendments and remarks, entry of the amendments and favorable consideration of the claims are respectfully requested. If the examiner has any questions or concerns regarding this amendment, he or she is invited to contact the undersigned at the telephone number listed below. If any fees are due or any overpayment made in connection with this paper, please charge or credit our Deposit Account No.: 082461.

Respectfully submitted,

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